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and other biocompatible metals, chromium cobalt alloy, or collagen. Webbing materials can include silicone, collagen, ePTFE, DACRON, polyester, polypropylene, polyethylene, and other biocompatible materials and can be woven or non-woven. Membranes might be fashioned of silicone, propylene, polyester, SURLYN, PEBAX, polyethylene, polyurethane or other biocompatible materials. Inflation fluids for membranes can include gases, liquids, foams, emulsions, and can be or contain bioactive materials. The stent body, webbing and/or membrane can be drug eluting or bioresorbable, as known in the medical implant arts.

IN THE DRAWINGS:

Subject to the approval of the Examiner, please amend Figs. 13-15, 16C, 17C, and 21 as proposed in the accompanying Request for Approval of Drawing Change.

REMARKS

Entry and consideration of this amendment is respectfully requested.

The specification has been amended to correct numerous informalities, spelling and grammatical errors. Accordingly, no new matter is entered by amendment.

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If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 16, 2002

By: _____
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APPENDIX

Please replace paragraph [008] with the following amended paragraph:

An additional method of relieving the symptoms is thermal annuloplasty, involving the heating of sub-[ ]annular zones in the non-[ ]herniated painful disc, seeking pain relief, but making no claim of reconstruction of the ruptured, discontinuous annulus wall.

Please replace paragraph [039] with the following amended paragraph:

FIG. 20 shows an expanded annulus stent with barbs on the radial extensions.

Please replace paragraph [043] with the following amended paragraph:

Additionally, to repair a weakened or thinned wall of a disc annulus **42**, a surgical incision is made along the weakened or thinned region of the annulus **42** and one or more surgical sutures **40** can be placed at about equal distances laterally from the incision. Reapproximation or closure of the incision is accomplished by tying the sutures **40** so that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural [heal- lng] healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable, but permanent non-[ ]biodegradable materials may be utilized.

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Please replace paragraph [045] with the following amended paragraph:

In a further embodiment, as shown in FIGs. 8A-B a biocompatible membrane can be employed as an annulus stent **10**, being placed [']in and across the aperture **44**. The annulus stent **10** acts as a bridge in and across the aperture **44**, providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus **42**, prior to closure of the aperture **44**.

Please replace paragraph [050] with the following amended paragraph:

The lower section **16** of the centralized vertical extension **12** can comprise a pair of lateral extensions, a left lateral extension **20** and a right lateral extension **22**. The lateral extensions **20** and **22** comprise an inside edge **24**, an outside edge **26**, an upper surface **28**, and a lower surface **30**. The lateral extensions **20** and **22** can have an essentially constant thickness throughout. The inside edge **24** is attached to and is about the same length as the lower section **16**. The outside edge **26** can be about 8mm-16mm in length. The inside edge **24** and the lower section [B] **16** meet to form a horizontal plane, essentially perpendicular to the centralized vertical extension **12**. The upper surface **28** of the lateral extensions **20** and **22** can form an angle from about 0°-60° below the horizontal plane. The width of the annulus stent **10** may be from about 3mm-5mm.

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Please replace paragraph [055] with the following amended paragraph:

A porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus fibrosus as disclosed in, for example, U, S. Patent Nos. 5,108,438 (Stone) and 5,258,043 (Stone), a strong network of Miert fibers intermingled with a [bloresorbable] bioresorbable (or [bloresorbable] bioabsorable) material which attracts tissue ingrowth as disclosed in, for example, U.S. Patent No, 4,904,260 (Ray et al.).

Please replace paragraph [060] with the following amended paragraph:

In further embodiments, as shown in FIGs. 5AB-6AB, the left and right lateral extensions **20** and **22** join to form a solid pyramid or cone. Additionally, the left and right lateral extensions **20** and **22** may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral extensions **20** and **22** to be compressed [foruilsertion] for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall.

Please replace paragraph [061] with the following amended paragraph:

Alternatively, a compressible core may be attached to the lower surface **30** of the lateral extensions **20** and **22**, forming a pyramid, cone, trapezoid, wedge, or bullet shape. The compressible core may be made from one of the biocompatible or [bloresorbable] bioresorbable resilient [foarris] foams well known in the art. The core

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can also comprise a fluid-expandable membrane, e.g., a balloon. The compressible core allows the lateral extensions **20** and **22** to be compressed for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

Please replace paragraph [064] with the following amended paragraph:

In an alternative method of securing the annulus stent **10** in the aperture **44**, as shown in FIG. 9, a first surgical screw **50** and second surgical screw **52**, with eyeholes **53** located at the top of the screws **50** and **52**, are opposingly inserted into the adjacent vertebrae **54** and **56** below the annulus stent **10**. After insertion of the annulus stent **10** into the aperture **44**, a suture **40** is passed down though the disc annulus **42**, adjacent to the aperture **44**, through the eye hole **53** on the first screw **50** then back up through the disc annulus **42** and through the orifice **18** on the annulus stent **10**. This is repeated for the second screw **52**, after which the suture **40** is secured. One or more surgical sutures **40** are placed at about equal distances along the sides of the aperture **44** in the disc annulus **42**. Reapproximation or closure of the aperture **44** is accomplished by tying the sutures **40** in such a fashion that the sides of the aperture **44** are drawn together. The reapproximation or closure of the aperture **44** enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap [']in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable but permanent [nonblo degradable] <u>non-biodegradable</u> forms may be

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[utilize&] utilized. This method should decrease the strain on the disc annulus **42** adjacent to the aperture **44**, precluding the tearing of the sutures through the disc annulus **42**.

Please replace paragraph [068] with the following amended paragraph:

In an illustrative embodiment, a hydrogel is injected into the internal cavity **62** of the flexible bladder **60**. A hydrogel is a substance formed when an organic polymer (natural or synthetic) is cross-linked via, covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice structure, which entraps water molecules to form a gel. The [hydroget] hydrogel may be used in either the hydrated or dehydrated form.

Please replace paragraph [072] with the following amended paragraph:

In an alternative embodiment, as shown in FIG. 13, the annulus stent **10** is substantially umbrella shaped, having a central hub [62] **66** with radially extending struts [67] **67**. Each of the struts [64] **67** is joined to the adjacent struts [64] **67** by a webbing material [66] **65**, forming a radial extension **76** about the central hub [62] **66**. The radial extension **76** has an upper surface **68** and a lower surface **70**, where the upper surface **68** contours to the shape of the disc annulus' **42** inner wall. The radial extension **76** may be substantially circular, elliptical, or rectangular in shape. Additionally, as shown in FIG. 20, the upper surface **68** of the radial extension **76** may

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be barbed **82** for fixation to the disc annulus' **42** inner wall and to resist explusion through the aperture **42**.

Please replace paragraph [073] with the following amended paragraph:

As shown in FIGs. 14 and 15, the struts [64] **67** are formed from flexible material, allowing the radial extension **76** to be collapsed for insertion into aperture **44**, then the expand conforming to the shape of the inner wall of disc annulus **42**. In the collapsed position, the annulus stent **10** is substantially frustoconical or shuttlecock shaped, and having a [leading] first end **72**, comprising the central hub [62] **66**, and a [trailing] second end **74**.

Please replace paragraph [074] with the following amended paragraph:

In an alternative embodiment, the radial extension **76** has a greater thickness at the central hub [62] **66** edge than at the outside edge.

Please replace paragraph [080] with the following amended paragraph:

In a method of use, as shown in FIGs. 16A-16C, the radial extension **76** is collapsed together, for insertion into the aperture **44** of the disc annulus **42**. The radial extension **76** is folded such the upper surface **68** forms the inner surface of the cylinder. The annulus stent **10** is then inserted into the aperture **44**, inserting the leading end **72** though the aperture **44** until the entire annulus stent **10** is within the disc

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annulus **42.** The radial extension **76** is released, expanding within the disc **44**. The upper surface **68** of the annulus stent **10** contours to the inner wall of disc annulus **42**. The central hub [62] **66** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42** using means well known in the art.

Please replace paragraph [082] with the following amended paragraph:

In an alternative method of use, as shown in FIGs. 17A-17C, the radial extension **76** is collapsed together for insertion into the aperture **44** of the disc annulus **42**. The radial extensions **76** are folded such that the upper surface **68** forms the outer surface of the [cylinder] stent, for example in a frustoconical configuration as illustrated. The annulus stent **10** is then inserted into the aperture **44**, inserting the tail end **74** through the aperture **44** until the entire annulus stent **10** is in the disc. The radial extensions **76** are released, expanding within the disc. The upper surface **68** of the annulus stent **10** contours to the disc annulus' **42** inner wall. The central hub [62] **66** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42**, using means well known in the art.

Please replace paragraph [084] with the following amended paragraph:

In a method of use, as shown in FIGs. 12A-12B, where the annulus stent **10** has been inserted into the aperture **44**, as has been previously described. Similarly, for the stent shown in FIGs. [16] 18 through 21, an injection instrument, as known in the art,

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such as a syringe, can be used to inject the biocompatible fluid or expansive foam into the internal cavity **86** of the flexible bladder **80**. The biocompatible fluid or expansive foam is injected through the annulus stent **10** into the internal cavity **86** of the flexible bladder **80**. Sufficient material is injected into the internal cavity **86** to expand the flexible bladder **80** to fill the void in the intervertebral disc cavity. The use of the flexible bladder **80** is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

Please replace paragraph [086] with the following amended paragraph:

Various materials know to those skilled in the art can be employed in practicing the present invention. By means of example only, the body portions of the stent could be made of NiTi alloy, plastics including polypropylene, polyethylene, stainless steel and other biocompatible metals, chromium cobalt alloy, or collagen. Webbing materials can include silicone, collagen, ePTFE, [Dacron] DACRON, polyester, polypropylene, polyethylene, and other biocompatible materials and can be woven or non-woven. Membranes might be fashioned of silicone, propylene, polyester, SURLYN, PEBAX, polyethylene, polyurethane or other biocompatible materials. Inflation fluids for membranes can include gases, liquids, foams, emulsions, and can be or contain bioactive materials. The stent body, webbing and/or membrane can be drug eluting or bioresorbable, as known in the medical implant arts.

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